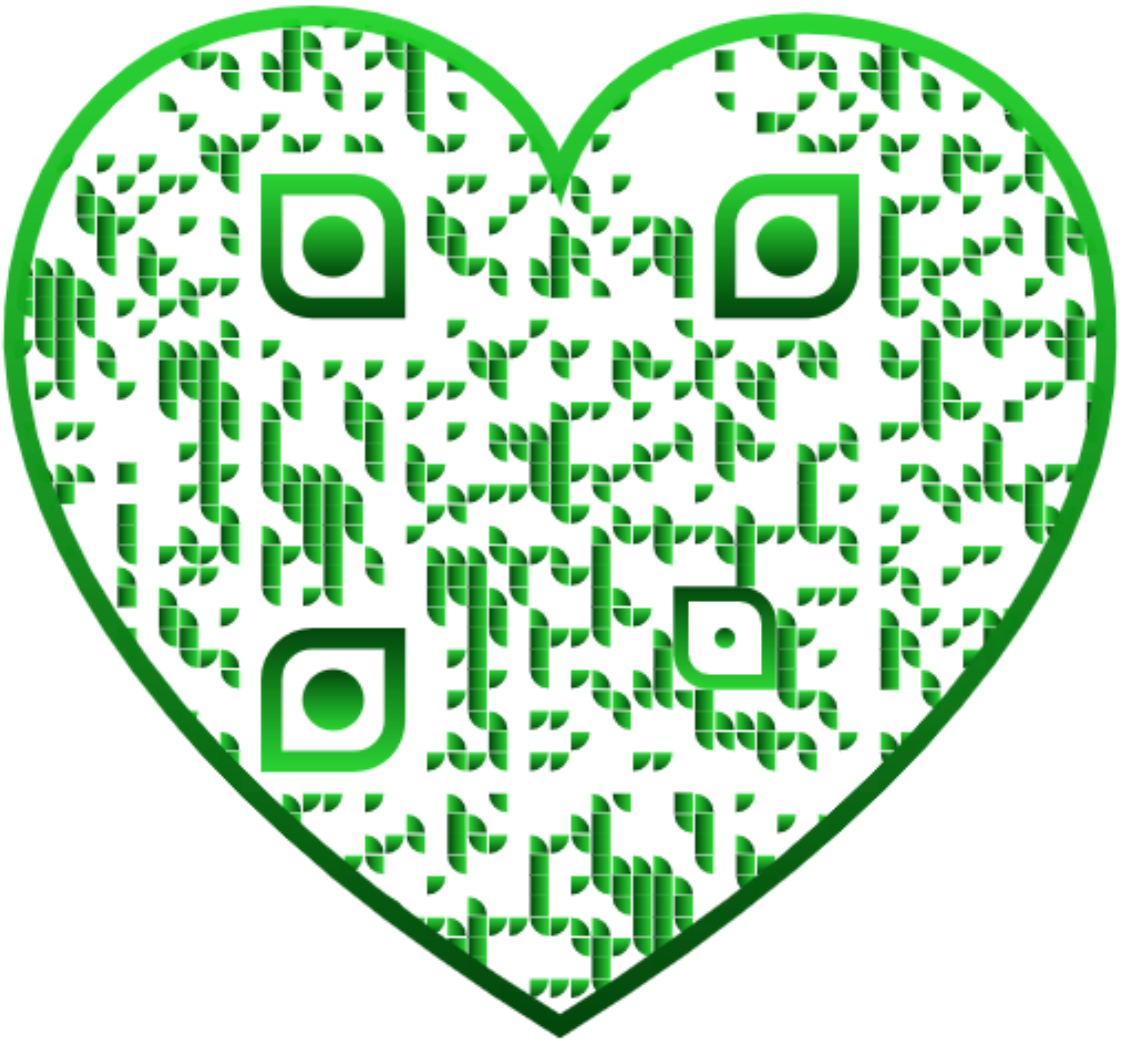
Domain 1: Pharmaceutical Laws and Regulations

Domain 2: Ethics and Professionalism

Sisay E.



Domain 1: Pharmaceutical Laws and Regulations

Areas of Concentration

- **Licencing and re-licensing**
  - Requirements of **licensing** and **Re-licensing** of pharmaceutical establishments
    - Manufacturing, Import, Wholesale and Retail business
  - Requirements of licensing and Re-licensing of professionals
  - Pharmaceutical inspection (GMP inspection)
    - Principles of GMP
    - Types of inspection
    - Frequency of inspection

Areas of Concentration…

- **Registration of medicines and Medical devices**
  - Types of application (IND, NDA, ANDA)
  - Variation application (Major Vs Minor)
  - Bio-waiver consideration during application
    - BCS consideration
      - Class I, II,III and IV
  - Interpretation of Bioequivalence results in MA
    - Cmax
    - Tmax
    - T1/2

Areas of concentration…

- Interpretation of QC tests in MA
  - Physicochemical tests
  - Analytical tests

Areas of Concentration …

- **Pharmacovigilance (Adverse drug event reporting)**
  - Reportable adverse events
    - ADRs, PQD, Medication error
  - Minimum requirements of ADR reporting
  - PV methods (Active Vs Passive)
- **NPS handling and management**
  - Manufacturing of NPS
  - Prescribing requirements of NPS
  - Dispensing requirements of NPS
  - Storage and distribution requirements of NPS

Areas of Concentration …

- Regulation of Promotion/advertising of pharmaceuticals
  - What is permitted/prohibited
  - Contents of advertisement/promotion

AREAS OF CONCENTRATION …

- **Definition of common terminologies common terminologies**

- QMS
- QA
- QC
- Validation
- Qualification
- Pharmacovigilance
- Medication error
- Product quality defect
- Adverse drug event

Areas of Concentration …

- National and international pharmaceutical laws
  - Civil and criminal laws
  - Hierarchy of laws
    - Constitution
    - Proclamation
    - Regulation
    - Directive
    - Guideline
    - SOPs

Ares of Discussion …

- **Domain 2: Ethics and Professionalism**
  - Basic concepts of ethics
  - Ethical theories
  - Basic principles of biomedical ethics

Licencing and Re-licensing Requirements

- **Requirements to obtain manufacturing license:**
  - Personnel
  - Personnel
  - Equipment
  - SOP to be followed

Licencing…

- **License/Authorization to import**
  - License is issued after assuring the fulfillment of the following:
    - Personnel
    - Premises,
    - Equipment, and facility
    - SOP
- **Wholesale requirement**
  - More or less similar to the control of the import of pharmaceuticals

Licencing…

- **Requirements to establish drug retail outlets**
  - **Certificate of competence**
    - Personnel
    - Premise
    - Equipment/facilities
    - SOP

Licencing of professionals

- Academic credentials (Degree)
- Licensure exam result (COC result)
- Renewal requirements:
  - Renewal resume every 3 years
  - Previous licence (certificate)
  - CPD course completion certificates (30 CEU/year, 90 CEU/Licensure period)

Managing of Narcotics and Psychotropic substances

- Separate and strict security storage areas
- Dispense using special prescription paper
- Keep proper registration
- Shall not dispense in excess quantities
- Not fill prescriptions for signed by prescriber for self use
- Keep expired and damaged products in separate safe place

Managing of NPS…

- NPS prescription paper contains the name of the prescriber and the institution's stamp
- Prescription is original
- Separate prescription paper for narcotic and psychotropic
- No more than one type of NPS prescribed using one prescription paper
- Prescription paper contains readable series number
- Issue date for **NPS:15 days**

Managing of NPS…

- **NPS import requirements:**
  - Require special pre-import permit
  - Special import permit will be effective for 90 days (3 months)
  - Imported through air
  - Not packed with other products

Type of Inspection

- **Routine inspection**
  - Full or comprehensive review/inspection of all aspects and components of the pharmaceutical establishments
    - Including medicine retail outlets, distributors, wholesalers, importers, exporters or manufacturer etc.
  - Conducted under an announcement
  - Applied when a newly established manufacturing facility or a manufacturer who has expressed interest of expanding manufacturing activities including:
    - Introduction of new products,
    - Modification of manufacturing methods or processes; or
    - Changes in key personnel, premises and/or equipment and
    - When GMP certification has expired within 5 years

Type and Frequency of Inspection…

- **Follow up inspection**
  - Conducted specifically to monitor the result of corrective actions of the manufacturer following a previous inspection
  - Limited to specified GMP non compliances that have been observed
  - If the inspection is carried out within 6 months after receiving official inspection reports, otherwise a full inspection shall be initiated.
  - Depending on pre agreement process due to the nature of the previous observation at submitted corrective and preventive action (CAPA), the framed time may be longer than 6 months after receiving official inspection reports.
  - Any applicant shall apply only for two round follow up inspection

Type and Frequency of Inspection…

- **Concise inspection**
  - Conducted when a **limited number of requirements** selected to serve as indicators of the overall compliance to the manufacturer
  - Reserve for establishments that have been previously inspected for good manufacturing practice.
  - Inspectors identify and evaluate any significant changes that might have been introduced by the establishment since its previous inspection
  - If the concise inspection uncovers evidence that the level of compliance has fallen, comprehensive or full inspection should be performed soon after the concise inspection

Type of inspection…

- Sudden Inspection (Investigative)
  - Inspection is undertaken to **deal with specific complaints received about gaps or non-compliance with standards** of professional practice or performance of new establishment whose scope of operation was previously unknown, complaints, product failure or recall.
  - Conducted when there are complaints about a specific product that suggest a defect, when there is a product recall due to adverse drug reaction, PMS , to gather specific information, or to investigate specific operations of the manufacturing processes
  - It shall not be announced

Frequency of inspection

- Manufacturers sites shall be inspected once every 5 year for the purpose of registration of their products.
- Depending on the type of inspection to be performed manufacturers may be inspected more than once in a 5 year period.

Principles Good manufacturing Practices (GMP)

- **Good Manufacturing Practice (GMP)**
  - Part of QA which ensures medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing Authorization or product specification

Components of GMP

- **1. Quality Management system**
- **2. Premises:**
  - Must be located, designed, constructed, adapted and maintained to suit the operations to be carried out
  - The layout and design must aim to minimize the risk of errors and permit effective cleaning and maintenance
    - To avoid cross-contamination, build up of dust or dirt and, in general, any adverse effect on the quality of products
  - Designated area for the following major tasks
    - Production Area
    - Storage Area
    - Quality Control Area
    - Ancillary Area

Components of GMP…

- **3. Faculties and Equipment**
  - Equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out
  - Repair and maintenance operations should not present any hazard to the quality of the products.
  - It should be cleaned according to detailed and written procedures and stored only in a clean and dry condition.
  - Washing and cleaning equipment should be chosen and used in order not to be a source of contamination.
  - Equipment should be installed in such a way as to prevent any risk of error or of contamination

Components of GMP…

4. Sanitation and Hygiene

- Detailed hygiene programmes should be established and adapted to the different needs within the factory.
- All personnel should receive medical examination upon recruitment

5. MATERIALS: Raw materials and components

- Starting materials
- Packaging materials,
- Gases, solvents,
- Process aids,
- Reagents and labelling materials
- Rejected, Recovered, Reprocessed and Reworked Materials
- Recalled Product
- Returned products
- Reference Standards

Components of GMP…

6. Manufacturing process

- Production operations must follow clearly defined procedures; they must comply with the principles of GMP
  - To obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorizations
- Prevention of Cross Contamination in Production
- Validation
- Starting Materials
- Processing Operation-Intermediate and Bulk
- Packaging Operations

Components of GMP…

7. Personnel

- Sufficient qualified personnel to carry out all the tasks
- Individual responsibilities should be clearly understood by the individuals and recorded.
- All personnel should be aware of the principles of GMP
- **Key Personnel:**
  - Production
  - Head of Quality Control
  - Head of engineering

Components of GMP…

- **8. Packaging and labeling**

- **9. Training**

  - Provide training for all the personnel whose duties take them into production areas or into control laboratories

Components of GMP…

- **10. Quality Control (QC)**
  - Independence of QC from production
  - Good Quality Control Laboratory Practice
  - Documentation
  - Sampling
  - Testing
  - Stability Study Monitoring

Components of GMP…

- **11. Contract Production and Analysis**
  - Must be correctly defined, agreed and controlled
  - There must be a written contract between the Contract Giver and the Contract Acceptor
  - The contract must clearly state the way in which the authorized person releasing each batch of product for sale exercises his full responsibility.

Components of GMP…

- 12. Complaints and product recall
  - All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures.
- 13. Self Inspection and Quality Audits
  - Conducted to monitor the implementation and compliance with GMP principles and to propose necessary corrective measures.
  - All recommendations for corrective action should be implemented.
  - The procedure for self-inspection should be documented, and there should be an effective follow-up programme

Components of GMP…

- **14. Validation and Qualification**
  - It is a requirement of GMP that manufacturers identify what validation work is needed to prove control of the critical aspects of their particular operations.
  - Significant changes to the facilities, the equipment and the processes, which may affect the quality of the product, should be validated
  - **Process validation:**
    - Prospective validation
    - Concurrent validation
    - Retrospective validation
  - **Qualification:**
    - Design Qualification, Installation Qualification, Operational Qualification, Performance Qualification

Components of GMP…

- **Cleaning Validation**
  - Performed in order to confirm the effectiveness of a cleaning procedure

- **15. Documentation and record keeping**
  - Good documentation constitutes an essential part of the quality assurance system.
  - Clearly written documentation prevents errors from spoken communication and permits tracing of batch history. Specifications, Manufacturing Formulae and instructions, procedures, and records must be free from errors and available in writing.
  - The legibility of documents is of paramount importance

Registration of Medicines and Medical devices

- General recommendation for the submission of the dossier:
  - For generic products in which a molecule of an FPP is registered in Ethiopia, Module 4 is not applicable
  - For generic FPP where bioequivalence is not required, Module 4 and Module 5 are not applicable; and
  - For generic products in which a molecule of an FPP and where a bioequivalence (BE) study is mandatory, Module 4 and Module 5 are not applicable except that the BE study report should be provided with the other modules of the dossier

Registration of Medicines…

- **Fast Track Registration**: Applied for:
  - Antimalarial, antiretroviral
  - Anti-tuberculosis medicines
  - Maternal, neonatal and child health (MNCH) product
  - Anti-cancer drugs, vaccines, Hepatitis
  - New drug
  - Drugs for "orphan diseases" and
  - Drugs for emergent humanitarian aid shall have priority for evaluation and registration

Registration of Medicines…

- Modular format of product dossier:
  - Module 1: Administrative and product information
  - Module 2: Dossier Overall Summary of Product Dossier (DOS-PD)
  - Module 3: Quality
  - Module 4: Nonclinical Study Reports
    - Generally not applicable for multisource products (some exceptions may apply)
  - Module 5: Clinical Study Reports

Variation applications to registered medicines

- Variation :
  - Post approval changes to any aspect of a pharmaceutical product including:
    - Change to formulation, method, and site of manufacture or specifications for the finished product, ingredients, container and container labeling, and product information.

Variation applications to registered medicines….

- **Major variations :**
  - Changes that could have major effects on the overall safety, efficacy and quality of the FPP
- **Minor Variation (Vmin)**
  - Changes that may have minor effects on the overall safety, efficacy and quality of the FPP.
  - Variation to the registered pharmaceutical finished product in terms of administrative data and/or changes that could have minimal or no adverse effects on the overall safety, efficacy and the quality of finished pharmaceutical product
  - Applicants must satisfy themselves that they meet all of the prescribed conditions for the change and submit all required documentation with the variation application.
  - This type of application require prior approval by the Authority

Waiver of In Vivo Bioequivalence Requirements

- **Biowaiver:**
  - Biowaiver is applied to a regulatory drug approval process where the efficacy and safety part of the dossier is approved based on evidence of *invitro* equivalence other than through in vivo equivalence testing
    - i.e. use of in vitro testing as a reliable surrogate for an in vivo BE study.
  - Major advantage of the biowaiver procedure:
    - Simplification of the product approval process and the reduction of the time required, thus reducing the cost of bringing new products to market.
  - Biowaiver can be applied only for products which meet requirements on pharmaceutical equivalent, as well as similarity in comparative dissolution tests.

Biowaiver Based on Biopharmaceutical Classification System (BCS)

- ***Biopharmaceutics classification system (BCS)***
  - It is a scientific framework for classifying APIs into four groups based on their aqueous solubility and intestinal permeability properties
  - According to the BCS, drug substances are classified as follows:
    - Class I: High solubility-high permeability
    - Class II: Low solubility - high permeability
    - Class III: High solubility-low permeability
    - Class IV: Low solubility-low permeability

Criteria for acceptance of BCS based biowaiver for a pharmaceutical product

- Dosage forms of APIs which are highly soluble, highly permeable (BCS Class I) with acceptable excipient content and favorable risk-benefit analysis and which are rapidly dissolving are eligible for a biowaiver based on the BCS provided:
  - The dosage form is rapidly dissolving and the dissolution profile of the multisource product is similar to that of the comparator product in aqueous buffers at pH 1.2 or Simulated Gastric Fluid USP without enzymes, pH 4.5 and pH 6.8 or Simulated Intestinal Fluid USP without enzymes using the paddle method at 75 rpm or the basket method at 100 rpm and meets the criteria of dissolution profile similarity, f2 ≥ 50 (or equivalent statistical criterion);

- If both the comparator and the multisource dosage forms are very rapidly dissolving (85% in 15 minutes) the two products are deemed equivalent and a profile comparison is not necessary

- Dosage form of APIs that are highly soluble and have low permeability (BCS Class III) are eligible for biowaiver provided that the following three and the risk-benefit is additionally addressed in terms of extent, site and mechanism of absorption
  - Both the comparator and the multisource dosage forms are very rapidly dissolving
  - All the excipients in the proposed product formulation should be qualitatively the same and quantitatively similar to that of the comparator product, as defined by WHO quality limits on allowable quantitative changes in excipients for a variations
  - The risks of incorrect biowaiver decision in terms of the therapeutic index of and clinical indication for APIs is absent.

- Fixed dose combination (FDC) product with class I and or III APIs meeting the dissolution criteria as specified above.
- Evidence to show that the excipients included are the same (i.e. same ratios and amounts) as the comparator product or that the excipients used do not influence the absorption of the AP

- **Bioavailability :**
  - It is the rate and extent of drug available at the site of action
- **Bioequivalence**
  - It is the absence of a significant difference in the rate and extent of drug available at the site of action after dosing of a ***test product***, compared to a ***reference product***.

Types of surveillance/Pharmacovigilance methods

- Passive surveillance Vs Active surveillance
- Passive Surveillances:
  - Spontaneous reporting
  - Stimulated reporting
  - Intensified reporting
  - Targeted spontaneous reporting

Pharmacovigilance methods

- **Active Surveillances:**
  - Sentinel sites
  - Drug event monitoring
  - Registries

Pharmacovigilance Methods

- **Spontaneous reporting system**
  - A system to monitor the safety of all medicines on the market
  - Voluntary submission of ICSRs by health professionals, pharmaceutical manufacturers and patients to the national pharmacovigilance center

Pharmacovigilance Methods…

Pros with spontaneous reporting

- Covers the whole population
- Includes all medicines
- Continual monitoring throughout life-cycle of a medicine
- Detects signals of new, rare or serious ADRs

Pharmacovigilance Methods…

Pros with spontaneous reporting

- Most commonly used method
- Easiest method to establish
- Least labour intensive
- Relatively inexpensive

Pharmacovigilance Methods…

Cons with spontaneous reporting

- Inherent under-reporting
- Captures only suspected ADRs
- Reporting bias
  - Seriousness, severity
  - New medicine
  - Advertising of product
  - Publicity of specific ADR

Pharmacovigilance Methods…

Cons with spontaneous reporting

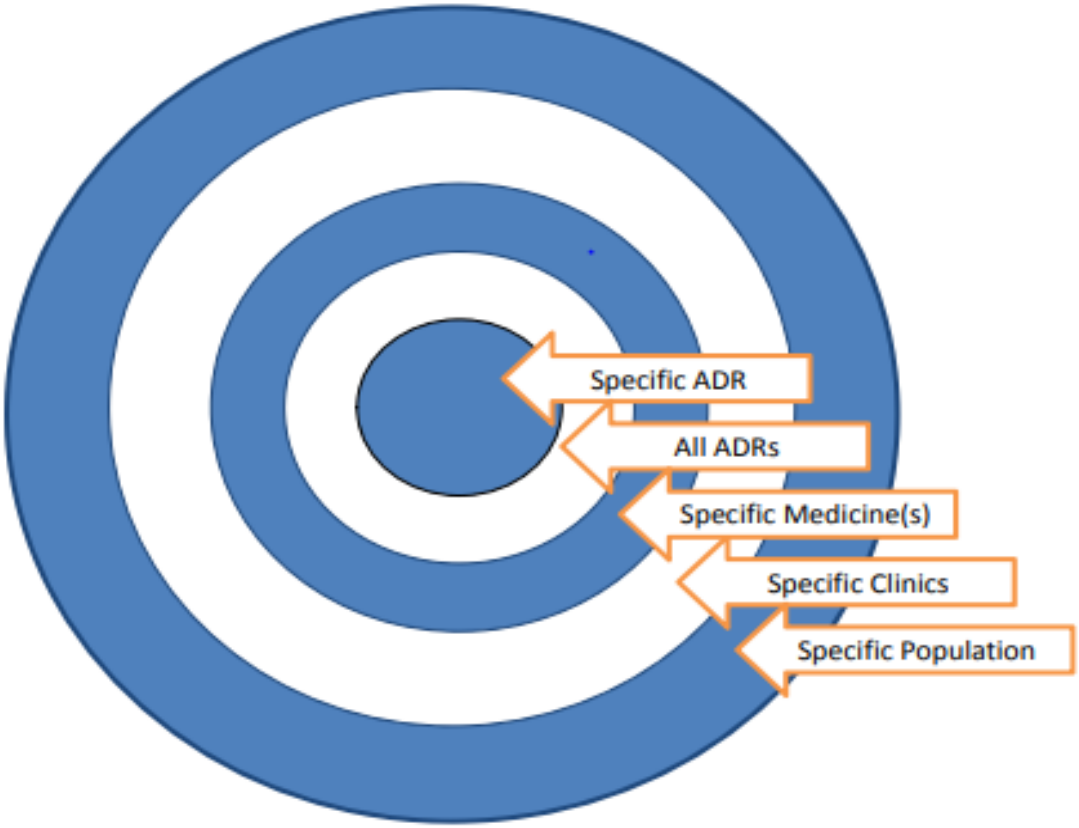
- Denominator unknown
- Difficult to detect
  - delayed ADRs
  - ADRs with high background incidence

Pharmacovigilance Methods…

- **Intensified spontaneous Reporting**
  - To enhance ADR reporting of specific medicines in early post marketing phase
  - Extension of Spontaneous Reporting Programme
    - Example: Antiretroviral medicines under a separate program
- **Targeted Spontaneous reporting (TSR):**
  - Intensified ADR Reporting within a defined cohort
    - Example: Monitoring renal toxicities related to the use of tenofovir based regimen in antiretroviral therapy

Pharmacovigilance Methods…

Targeted Reporting



Pharmacovigilance Methods…

Pros with TSR

- Can utilise existing ADR reporting infrastructure
- Targets specific medicines of interest
- Possible to implement monitoring programme that targets specific issue of concern (ADR, medicine, patient group)
- Captures useful information (less 'background noise')
- Denominator known

Pharmacovigilance Methods…

Cons with TSR

- Under-reporting remains a problem
- Captures only suspected ADRs or known toxicities
- May limit reporting only to specific ADRs
- Relies on diagnostic capability of reporter

Pharmacovigilance Methods…

Cohort Event Monitoring (CEM)

- To gather more information on the safety profile of a new chemical entity in early post-marketing phase

- Observational cohort study design
- Patients enrolled into cohort and actively followed-up during treatment to record all adverse events (not just suspected ADRs).

Pharmacovigilance Methods…

Cohort Event Monitoring (CEM)

- Characterise known reactions
- Detect signals of unrecognised reactions
- Identify interactions with other medicines and TCAMs
- Detect inefficacy of medicine
- Assess safety in pregnancy & lactation
- Identify risk factors for ADRs

Example: ADR monitoring of anti-retroviral drugs

Pharmacovigilance Methods…

- **Sentinel sites:**
  - It involves the collection of AE data from only part of the total population to learn something about the larger population.
  - Example: to study the trends in a disease.
- **Drug event monitoring:**
  - The patients are identified from electronic prescription data or automated health insurance claims.
  - Patients will fill the survey form
  - Follow up questionnaire is then sent to prescribing physician.

Pharmacovigilance Methods…

- **Registries:**
  - A registry is a list of patients with the same characteristics.
  - The registries may be disease specific (disease registry) or drug specific (drug registry) or type of exposure during a specific life event (pregnancy exposure registry).
  - The information is collected using standardized questionnaires.

Pharmacovigilance Methods…

Method	Medicines	Population	Reports
Spontaneous Reporting	All medicines, life-cycle of product	All exposed individuals but denominator unknown	All ADRs
Intensified ADR Reporting	Specific medicines	All exposed individuals but denominator unknown	All ADRs
Targeted Reporting	Specific medicines	Defined cohort	All ADRs
			Specific ADRs
Cohort Event Monitoring	Specific medicines	Defined cohort	All Events

Components of an ADE report

- Adverse drug event report shall contain the following data
  - Patient information
    - Patient name in abbreviation, card No. , Age /date of birth, Weight, Height, Ethnic group, Substance of abuse
  - Drug information on suspected and concomitantly used drug
    - Batch number, brand name, manufacturing date,
    - Expiry date and manufacturer,
    - Dose/dosage form, route, frequency,
    - Date drug taking was started/date drug reaction started,
    - Date drug was stopped, indication and
    - Product quality information if it is a quality issue

Components of an ADE report…

- Adverse drug event information
  - Clear and brief description about the nature of adverse event symptoms experienced,
  - Duration, time course and laboratory test results including "negative" and normal results of any relevant test performed;
  - Severity of the reaction including necessitated prolonged hospitalization or not, discontinuation of the medicine or not,
  - Reaction subsided after the drug was discontinued or not, reaction reappeared after the restart of the drug or not for causality assessment purposes; treatment of reaction; outcome; squeal and relevant medical conditions

Components of an ADE report…

- **Reporter's information**
  - Name, Profession, email address, telephone, name of health institution, P.o. box No. and date) as requested in the report form.

Reporting timeline

- Serious Adverse event:
  - Shall be notified within 24 hours and shall be reported within 48 hours
- Non-serious adverse events
  - Shall be reported within 7 working days

Reporting timeline …

- **Market Authorization Holder**
  - Shall report periodic safety update report, Individual case safety report in line with the national standards:
  - Unexpected and expected serious ADEs
    - should be notified within /48 hours
    - Must be reported as soon as possible but no later than 15 calendar days of initial receipt of the information.
    - Non-serious adverse drug events must be reported within 90 days after the granted knowledge of the event.

Reporting timeline

- For new medicines that are registered and placed in the market in the country,
  - Periodic Safety Update Report should be submitted to the authority
    - Every 6 months for the first two years after market approval and there after annually for three years.
    - If no adverse drug events have been received by the market authorization holder, it is obliged to submit a "Null" report

Control of Advertisement and promotion of Pharmaceuticals

- Content of every advertisement and promotion of a regulated product
  - Shall not be false and misleading,
  - Be appropriate and ethical, and
  - Comply with requirements of the proclamation and other applicable laws
  - Only a medical representative who has been granted a certificate of competency from the authority is entitled to promote drugs the health professional
  - Prior to any promotion, any licensed medical representative should submit an application to the planning, drug information department attaching the sample promotional material with the application form

Ethics and Professionalism

Sisay E.

Presentation Outline

- Introduction to ethics
- Ethical theories
- Basic principles of ethical principles and moral values in healthcare

Introduction

- **Ethics;**
  - Derived from the Greek word "ethos" meaning "**custom**" or "**character**".
  - Branch of philosophy deals with **standards of conduct** and **moral judgment**.
  - Systematic study of value concepts, 'good', 'bad', 'right', 'wrong' and the general principles that justify applying these concepts.
  - It is **norms of conduct** that distinguish between acceptable and **unacceptable behavior**

Types of Ethics

- **Descriptive ethics**:
  - **Description of the values and beliefs** of various cultural, religious or social groups about health and illness
- **Normative ethics**:
  - Study of **human activities** in a broad sense in an attempt to identify human actions that are right or wrong and good and bad qualities
- **Analytical ethics** :
  - Analyzes the meaning of moral terms.
  - eeks the reasons why action or attitudes are either wrong or right.

Examples: Identification of ethics category

1. Patients in pastoralist regions **believe** that capsules are more effective than tablets (highly adherent for capsules)
2. Ethnic group in SNNPR **extracts** the milk teeth of their teenagers when reach to adult age.
3. Patients in the northern part of Ethiopia **believe** that Injections are more effective than any oral preparations; especially tablets and capsules

Importance of Ethics

- To help health professionals identify moral and ethical issues
- To know what is right and wrong about what should and should not be done for and to the client,
- To know and respect the issues of human rights, personal and civic

Profession and its characteristics

- Form of **employment** or **field** that is **respected** in society and that requires **extensive study** and mastery of **specialization in knowledge**
- It is an **occupation** that requires special knowledge and skilled preparation.
- Professional: a person doing or practicing something as a full-time occupation or for payment or to make a living

- **Professionalism:** Applied to any field which requires a specialized body of knowledge and skill and the highest standards of conduct directed at the general benefit of the society

Characteristics of profession

- Specializing in **knowledge**
  - Rigorous training and schooling, problem-solving skills
- Providing essential **services** to the society
  - Deriving force: not fortune but rather the ministering
  - Provide service in the interest of the patient
- A high degree of self-control of behavior/standard of conduct
  - Codes, guidelines, oaths, etc

Ethical Theories

- **Deontology theory**
  - Duty-driven
  - Rule-based
  - Non-consequentialism theory
- **Teleological theory**
  - Consequentialism
  - End based actions theory
- **Utilitarian (Utilitarianism) Ethics**

Ethical Theories…

1. Deontology Theory

- **Duty driven/Non-consequentialism/ Theory**
- Proposes that the rightness or wrongness of an action depends on the ***nature of the act*** rather than its ***consequences***
- Considers the way that things are done rather than focusing just on the consequences
- Rightness and wrongness of act:
  - →Inherent in the **act** itself
  - →Independent of the **consequence**
    - ***Process matters more than the result: "The means justify the end"***

Ethical Theories…

2. Teleological theory

- **Consequentialism/End-based theory/**
  - Looks to the *consequences of an action* in judging whether that action is right or wrong
  - Actions are determined and justified by the consequence of the act:
    - ***"The result matters most": The end justifies the means***

Ethical Theories…

- **Utilitarian (Utilitarianism) Ethics:**
  - Governing ethical theory in public health
  - Holds that the proper course of action is the one that maximizes utility, specifically defined as maximizing happiness and reducing suffering
  - Considers the greatest good for the largest number of people

Impacts of Ethical Practices by Pharmacists

- **Impact on other health professionals**
  - Foster team work and ensure better outcome of therapy
  - Pharmacist gain better acceptance/recognition
- **Impact on fellow professionals and the profession**
  - **Professional:**

    →Develop better confidence,

    →Become more committed
  - **Profession:** guarantees continuity

Impacts of Ethical Practices by Pharmacists...

- **Impact on the patient and public**
  - Contributes to better treatment outcomes
  - Minimize risk and cost
  - Enables maintaining a healthy society …

Ethical Principles and Moral Values

Ethical principles

- **Principle:** Standard that is to be observed
- **Ethical Principles**;
  - Are basic ideas that are starting points for understanding and working through a problem.
  - Are tents that are important to uphold in all situations

Major Principles of Health Professionals' Ethics

1. Autonomy: (Respect for persons)

- Also known as self-government
- It is the ability to make decisions for oneself
- The right to participate in and decide on a course of action **without undue influence**
  - The right of individuals to **self-rule/self-determination**
- Respecting the decision-making capacities of autonomous persons;
  - enabling individuals to make a reasoned informed choice

Autonomy…

- Autonomy requires decision-making capacity
  - Lack should be proven notassumed
- Respect for autonomy requires that **patients be told the truth** about their condition and be **informed about the risks and benefits of treatment** in order for them to make informed decisions.
- Two important conditions must be met for the autonomy
  - ✓ Are pts. competent to make decisions for themselves?
  - ✓ Are pts. free from coercion in making the decision?
    - These questions reflect the idea that autonomy implies the freedom to choose

2. Beneficence (Doing good)

- Refers to actions that promote the well-being of others
  - *The act of being kind*
- Stress the importance of acting in the patient's best interest
- Health care providers have a duty to be of a benefit to the patient, as well as to take positive steps to prevent and to remove harm from the patient

Beneficence (Doing good)…

- The principle of beneficence has three components:
  - Promote health
  - Prevent harm
  - Remove evil or harm
- Actions are right if they **produce benefits**
  - **Example:**
    - The pharmacist who neglects to counsel patients is violating the principle of beneficence; b/c info about medications generally helps patients use their medications the correct way

3. Non-Maleficence (Doing no harm)

- ***"First, do no harm"*** principle
- It is to avoid causing deliberate **harm, risk of harm**, and harm that occurs during the performance of beneficial acts.
- Actions are wrong as they **induce bad consequence**
- Prohibits both deliberate and unintentional harm'
  - Example: Pharmacists and Physicians are obligated not prescribe and dispense medications they know to be harmful

3. Non-Maleficence …

- **Example 1**:
  - A pharmacist who fails to counsel patients, for fear that the patients will discontinue using a drug if the info is disclosed, is adhering to the principle of non-maleficence
- **Example 2**:
  - Killing and letting die (active and passive euthanasia)
  - Withholding or withdrawing life-sustaining treatment. (O2, Glucose , IV drug)
  - Providing a high dose of steroids to an asthmatic patient

4. Justice (Fairness)

- It involves the fair distribution of care
  - ✓ Equity and fairness in treatment
- It is the basis for the obligation to treat all clients in an equal and fair way.
- Address questions of distribution and allocation of **scarce medical resources**
- A decision is based on client needs and fair distribution of resources
- It is a fair, equitable, and appropriate treatment

4. Justice (Fairness)…

- Justice is a complex ethical principle, with meanings that range from the fair treatment of individuals to the equitable allocation of healthcare dollars and resources
- Be able to justify your actions in every medical situation
- Equitable **distribution of burdens and benefits**

Justice (Fairness)…

- **Two major categories of Justice**
  - **Procedural justice & distributive justice**
    - ***Procedural justice:*** Asks where **fair procedure in place** and where those procedures followed?
      - Due process
      - **Example:** keeping your turn in order to get your primary physician

Justice (Fairness)…

- ***Distributive justice***
  - Addresses the degree to which healthcare services are distributed equitably throughout society
  - Concerned with the **allocation of resources**
  - Form of ***rationing*** of the delivery of health care services.
  - All involved should have equal entitlements, equal access to benefits and burdens
  - Addresses the degree to which healthcare services are distributed equitably throughout society.

Justice (Fairness)…

- Dividing burdens and benefits
    - Each person should get an equal share of the burdens and benefits unless there is a material reason to discriminate
- E.g. How to determine who qualifies for one available kidney?
    - 55 yrs old man with three children Vs a 13 yrs old girl?

Justice (Fairness)…

- **Comparative Justice**
  - Making a decision based on criteria and outcomes
- **Non-comparative Justice**
  - Method of distribution using a lottery system
- Any health professional should treat all patients equally irrespective of sex, culture, race, religion, language, social status and political status

Justice…

- The four main areas that Health care providers must consider when evaluating justice

1. Fair distribution of scarce resources
2. Competing needs
3. Rights and obligations
4. Potential conflicts with established legislations

5. Veracity (truth-telling)

- Obligation to full and honest disclosure
- It is telling the truth, which is essential to the integrity of the client-provider relationship
- It is at its core respect for all persons by being truthful.
- It is the opposite of the concept of paternalism, which assumes patients need to know only what their physicians choose to reveal.
- Health care providers are obliged to be honest with clients
- An ethical principle that instructs pharmacists to be honest in their dealings with patients

5. Veracity (truth-telling)…

- The patient has the right to the truth;
  - ✓ Medical condition
  - ✓ The course of the disease and treatments

Veracity (truth-telling)….

- Code of ethics states:
  - A pharmacist: "has the duty to tell the truth and to act with conviction of conscience"
  - **Example:** if you have been informed about the result of an HIV test taken by someone in your community who then asks to know his/her result, you should tell the person the truth even though this might be very upsetting to that person.

6. Informed Consent

- It is an agreement to a certain course of action, such as treatment or participation in research, on the basis of complete and relevant information by a competent individual without coercion
  - Requires honesty and autonomy to exist
  - The right of the client to be informed and to freely choose a course of action

Informed consent…

- Informed consent exists when:
  - All **relevant information** has been provided
  - The patient **understands** the information
  - The patient is **capable** of understanding the info
  - Consent is **freely** given and there is **no coercion**

7. Confidentiality

- Maintain the confidentiality of all personal, medical and treatment information

  - Show trust by imparting secrets; tell in the assurance of secrecy

  - Confidentiality in the health care context is the requirement of HPs to keep information obtained in the course of their work

  - From patients' perspective, this is "self-disclosure" and they should be the ones making this decision

  - Client's right to give/refuse consent to release information

7. Confidentiality…

- Information to be revealed with consent and for the benefit of the patient
- Except when ethically and legally required
- Disclosure should not be beyond what is required

Confidentiality…

- The main ethical issue surrounding confidentiality is whether ***more harm is done by occasionally violating its mandate or by always upholding it, regardless of the consequences.***
  - This limitation to confidentiality is known as the *Harm Principle*
- Unfortunately, breaches of confidentiality more often result from careless slips of the tongue than from rational decision making.
  - Such social trading in gossip about patients is unprofessional, unethical, and, in certain cases, illegal.

Confidentiality…

- **When confidentiality may be breached???**
  - There is a professional duty to maintain confidentiality unless:
    - A court of law orders them to make a disclosure, (e.g. in a paternity dispute)
    - An Act of Parliament requires them to make a disclosure, (e.g. reporting child abuse)
    - There is a moral or legal obligation on the doctor to make a disclosure to a person or agency that has a reciprocal moral or legal obligation to receive the information, (e.g. where a patient threatens to kill someone)
    - The patient consents to the disclosure being made

8. Fidelity

- Healthcare professional's fiduciary duty to be a responsible and faithful custodian of the public trust.
- The special relationship developed between patients and their healthcare professionals.
- Being faithful to one's commitments and promises
- The right of patients to have practitioners provide services that are in the patients' best interest
- It speaks to the special relationship developed between patients and their healthcare professionals

8. Fidelity…

- **Example;**

→Recommending vitamins patients don't need

→Failing to confront prescriber with inappropriate Rx out of fear that s/he will direct patients elsewhere